

LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE
WESTBURY, NY 11590

(516) 222-6222
FAX (516) 683-1887

February 10, 2000

OVERNIGHT DOCUMENT

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Prozac (Fluoxetine) Tablets, 20 mg, (NDA-20-974), by Eli Lilly and Company, have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book", contains all FDA-approved drug products. The Orange Book currently lists Prozac (Fluoxetine) Tablets, 20 mg in the Prescription Drug Product List section. A listing in this section of the Orange Book indicates that the specific drug product is the subject of an approved application. However, based on a survey of the marketplace, Prozac Tablets, 20 mg, are not available for sale to the consumer.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drugs application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or

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effectiveness before an ANDA that refers to that list drug may be approved [21 CFR 314.161(a)(1)].

As stated, Eli Lilly and Company's Prozac Tablets, 20 mg, are not available for sale in the marketplace. Because there is no current commercial distribution of this drug product, it is requested that the FDA determine whether Eli Lilly's decision not to market Prozac Tablets, 20 mg, was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

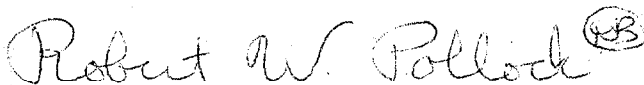
D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided if so requested.

E. Certification

The undersigned certifies that, to its best knowledge and belief, this petition includes all information and views on which the petition relies, and that includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Robert W. Pollock
Vice President

RP/db

Enclosure: *Cumulative Supplement No. 9, p. 22*

cc: L. Lachman
G. Johnston

Gcp0041

ETRETINATE

T >	CAPSULE; ORAL		
T >	TEGISON		
T >	ROCHE	10MG	N19369 001
T >			SEP 30, 1986
T >		25MG	N19369 002
T >			SEP 30, 1986
D >	@	10MG	N19369 001
D >			SEP 30, 1986
D >	@	25MG	N19369 002
D >			SEP 30, 1986

FERRIC SODIUM GLUCONATE

INJECTABLE; INJECTION
FERRLECIT
+ R AND D LABS

62.5MG/5ML

N20955 001
FEB 18, 1999

FLUOCINONIDE

OINTMENT; TOPICAL

AB FLUOCINONIDE
TARO

0.05%

N75008 001
JUN 30, 1999

FLUOROURACIL

INJECTABLE; INJECTION

AP FLUOROURACIL
BIGMAR

50MG/ML

N40291 001
MAR 24, 1999

AE SMITH AND NEPHEW

50MG/ML

N88767 001
DEC 28, 1984

AE

50MG/ML

N89434 001
MAR 26, 1987

@

50MG/ML

N88767 001
DEC 28, 1984

@

50MG/ML

N89434 001
MAR 26, 1987

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

PROZAC

* LILLY

EQ 20MG BASE

N18936 001

DEC 29, 1987

EQ 20MG BASE

N18936 001

DEC 29, 1987

EQ 40MG BASE

N18936 003

JUN 15, 1999

EQ 60MG BASE

N18936 004

JUN 15, 1999

TABLET; ORAL

PROZAC

LILLY

EQ 10MG BASE

N20974 001

MAR 09, 1999

EQ 20MG BASE

N20974 002

MAR 09, 1999

EQ 10MG BASE

N20974 001

MAR 09, 1999

EQ 20MG BASE

N20974 002

MAR 09, 1999

FOLIC ACID

TABLET; ORAL

FOLIC ACID

* VINTAGE PHARMS

1MG

N86296 001

> DLT >
> ADD >

@

1MG

N86296 001

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

AP

ABBOTT

10MG/ML

N75241 001

MAY 28, 1999

AE

SMITH AND NEPHEW

10MG/ML

N70078 001

FEB 05, 1986

@

10MG/ML

N70078 001

FEB 05, 1986

AE

STERIS

10MG/ML

N70019 001

SEP 22, 1986

AE

10MG/ML

N70504 001

JAN 02, 1997

@

10MG/ML

N70019 001

SEP 22, 1986

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